DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

Argon Medical Devices, Inc.
Ms. Suzanne Cheang
Regulatory Affairs Manager
1445 Flat Creek Road
Athens, TX 75751

Re: K141969
Trade/Device Name: FirstStic™ N Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 5, 2014
Received: December 8, 2014

Dear Ms. Cheang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141969

Device Name

FirstStic™ N Introducer

Indications for Use *(Describe)*

The catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date Prepared:	December 9, 2014
Company:	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, TX 75751 Facility Registration number: 1625425
Contact:	Suzanne Cheang Phone: 972-378-6980
Device trade name:	FirstStic™ N Introducer
Device Common Name:	Catheter Introducer
Device classification:	Catheter Introducer Product code, DYB 21 CFR 870.1340 Class II
Legally marketed device to which the device is substantially equivalent:	K020834 BD Introsyte-N™ Precision Introducer K093026 Footprint Medical 1.9Fr PICC Introducer
Description of the device:	The catheter introducer system is a notched introducer needle with a vented fitting and a splittable sheath introducer to facilitate percutaneous placement of a peripherally inserted central catheter (PICC) or midline catheter. The notched needle and clear sheath allow for easy insertion and a quick visual indication (flashback) when the vessel is penetrated. The catheter introducer is available to introduce 26ga/1.9Fr catheter.
Indications for Use:	The catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
Technological Characteristics:	Comparisons of the FirstStic™ N Introducer and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices. The FirstStic™ N Introducer is similar in design – device dimensional specifications, and intended use, shelf life and sterilization process of that of the predicate devices. It is equivalent in materials to the predicate devices.

Performance tests (Non-Clinical):

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. A series of testing was conducted in accordance with protocols based on requirements outlined in the guidance and industry standards and the results were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The FirstStic™ N Introducer is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and Indications for Use. The device design has been qualified through the following tests:

- Dimensional Analysis
- Lie Distance
- Needle Penetration Force
- Transition Penetration Force
- Sheath Crack Force
- Sheath Peeling Force
- Needle hub retention force
- Sheath hub retention force
- Visual confirmation of flashback
- Simulated Use

Biocompatibility testing per ISO 10993-1 was performed, consisting of the following tests:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Acute Systemic Toxicity/Material Mediated Pyrogen
- Hemocompatibility (Hemolysis Direct and Indirect)
- Thrombogenicity
- Complement Activation Assay (Direct Contact)

The results of this testing demonstrates that the FirstStic™ N Introducer, is substantially equivalent to the predicate devices and did not raise new safety or performance questions.

An additional particulate analysis was conducted for FirstStic™ N Introducer and the results did not raise new safety or performance questions.

Substantial Equivalence:

Based on the Indications for Use, design safety and performance testing, the subject FirstStic™ N Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate devices.